DETAILED ACTION

1. Applicant's amendment, filed 11/29/2010, has been entered.

Claims 1, 2, 4, 6 and 9-11 have been amended.

Claims 34-42 have been added.

Claims 1-42 are pending.

Applicant's amendment, filed 01/19/2011, has been entered.

As indicated previously, applicant's election of Group I with traverse in Response to Election Requirement, filed 03/30/2010, was acknowledged.

Claims 1-12 and 35-42 are under consideration in the instant application as the elected invention.

Claims 13-34 have been withdrawn from prosecution as being drawn to a non-elected invention.

2. While applicant's new title, filed 11/29/2010, is acknowledged.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

For example, there is no indication of a construct comprising a tumor antigen and CD40 ligand.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's arguments, filed 11/29/2010.

Upon reconsideration of applicant's arguments, the previous prior art rejections have been withdrawn.
New Grounds of Rejection have been set forth herein.

Note that CD154, CD40L and CD40 ligand all refer to the same molecule that binds CD40.

4. Upon reconsideration of applicant's amended claims, filed 11/29/2010, which is consistent with the instant disclosure concerning the structure of CD40L based upon U.S. Patent No. 5,962,406 (Armitage et al.) (1449; #A) (e.g., see paragraphs [0030][0034] of the instant specification),

the previous rejection under 35 U.S.C. § 112, second paragraph, in the recitation of "residues 1-23 and 47-261" of CD40 ligand has been withdrawn.

5. Claim 4 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite in the recitation of "thereby leaving carboxy terminus of CD40L free to bind to a CD40 receptor" because this recitation fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to the recitation of "free to bind to a CD40 receptor",
this particular phrase is not readily apparent in the specification as filed.

While this phrase appears to be only a characterization of CD40L:CD40 binding,
The recitation of "free" suggests applicant's intent for the recitation to be something other than a characterization of CD40L:CD40 binding and to be something to distinguish from the prior art.

Applicant should clarify the meaning this newly added phrase and amend the claims for clarity.

In addition, the recitation of "a CD40 receptor" appears to mean "CD40" itself and not a receptor to CD40.

To avoid confusion about the metes and bounds of "a CD40 receptor", applicant should amend the claims to recite "CD40 rather than a "a CD40 receptor" for clarity.

The recitation adds further confusion with the indefinite article "a", as it reads on something other than CD40 itself.

It is noted that if applicant's intent with the current recitation is other than a characterization of CD40L:CD40 binding or "CD40 itself",

then the claims would be subject to rejections under 35 U.S.C. § 112, first paragraph, written description for new matter and scope of CD40 receptors, respectively.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

6. Upon reconsideration of applicant's arguments, filed 11/29/2010 and 01/19/2011, in conjunction with the interview on 01/05/2011, the previous rejection rejection under 35 U.S.C. § 103(a) as being unpatentable over Curiel et al. (U.S. Patent No. 6,284,742) in view of Xiang (J. Immunol. 167: 4560-4565, 2001), Zheng et al. (Cancer Research 61: 8127-8134m 2001), Hu et al. (PNAS 96: 8161-8166, 1999), Dreyfus et al. (US 2002/0068048) and Thomas (US 2005/0048645) has been withdrawn.

See applicant's remarks, filed 11/29/2010 and 01/19/2011 addressing each reference as well as assertions of unexpected results over prior art of record.

7. Claims 1-2, 4-12 and 35-42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ledbetter et al. (U.S. Patent No. 7,118,751) in view of Curiel et al. (U.S. Patent No. 6,284,742) (892; of record), Crystal et al. (US 2003/0202963) and Korokhov et al. (US 2004/0147025).

Note that CD154, CD40L and CD40 ligand all refer to the same molecule that binds CD40.

Ledbetter et al. teach fusion protein expressed from a cDNA wherein the nucleic acid encodes an antigen domain , including tumor and tumor-associated antigens (e.g., see first and second paragraphs of Description of Prior Art in column 1; first paragraph of Summary in column 6; column 9, paragraph 1; column 10, paragraphs 2 and 4),

wherein an amino-terminal signal peptide upstream and adjacent to a cDNA sequence encoding the desired antigen, which is fused to the extracellular domain of CD154 or a portion of the extracellular domain of CD154 (including human CD154 and short or truncated forms)which retains the ability to bind CD40, that targets the antigen to antigen presenting cells (e.g., see Examples 1-2 and Figure 1),

wherein the embodiments can include other secretory signal peptides or localization sequences (e.g., see column 10, lines 58-62) in order to provide long-lasting protection against tumors as well as infection with microorganisms (e.g., see Summary, overlapping paragraph on columns 6-7 and Description, column 9, paragraph 1) (see entire document).

Ledbetter et al. differs from the claimed invention by not describing adenoviral viral vectors per se as the viral vector of choice (e.g., see paragraph 1 of the Description on column 8 of Ledbetter et al.).

Curiel et al. teach recombinant adenoviral vectors, comprising CD40L and a tumor or infectious agent antigen to manipulate the immune response for a person in need having a disease such as cancer or an infectious disease (e.g., see entire document, including Summary of the Invention and Detailed Description of the Invention, including columns 10-11).

The following provide further evidence of applicability of adenoviral vectors comprising CD40L at the time the invention was made.

Crystal teach the applicability of dendritic cell mediators, including CD40L (e.g., see paragraphs [0079]-[0080], [0091], wherein the CD40L can be provided by / administered via adenoviral vectors (e.g., see paragraphs [0100]-[0105], [0111]—0113]), as well as providing the antigen via the adenoviral viral vector, including co-administration antigen and dendritic cell modulator (e.g., see paragraph [0109]-[0110]) in order to treat conditions that can benefit from enhanced immune response, including cancer and immunocompromised patients (e.g., see paragraphs [0114]-[0116], [0124], [0132]-[0135]) (see entire document, including Background of the Invention, Brief Summary of the Invention, Detailed Description of the Invention and Examples).

Korokhov et al. teach the applicability of CD40-targeted vectors delivering antigen-expressing genes to dendritic cells in a more efficient manner to generate immune responses against tumor antigens, including the applicability of CD40L to target adenoviral vectors for selective and efficient gene transfer to dendritic cells (e.g., see Targeting Adenoviral Vectors for Genetic Anti-Cancer Immunization in paragraphs [0030]-[0043]) , including the specific example of Targeted Adenoviral Vectors Expressing Prostate Cancer-Specific Tumor Antigens (e.g., see paragraphs [0044]-[0055] and Examples 8-13), wherein the sequence encodes the soluble form of CD40L and wherein the adenoviral vector expressing a secretory form (e.g., see paragraphs [0010]-[0011], [0023]-[0028], [0080]-0081]) (see entire document, including Background of the Invention, Brief Summary of the Invention, Detailed Description of the Invention and Examples).

Given the teachings herein, it would have been obvious to one of ordinary skill in the art to make and use adenoviral expression vectors comprising CD40L, including the extracellular domain of CD40L with a tumor antigen to stimulate antitumor responses to tumors of interest. By employing the extracellular domain of CD40L, the expression vectors would not have the transmembrane or cytoplasmic regions of CD40L and would also provide for the secretion or soluble nature of CD40L. Human cytomegalovirus promoters/enhancers were known and obvious regulators of transcription in expression vectors of interest at the time the invention was made. The prior art teaches the advantages of stimulatory properties of CD40L to stimulate immune responses, including in therapeutic regimens of treating tumors. The prior art teaches the advantages of adenoviral vectors in delivery of modulators of tumor immunity.

The claimed functional attributes of the newly added claims are either explicitly or implicitly taught or encompassed by the prior art teachings of the prior art teachings of CD40-targeted vectors delivering antigen-expressing genes to dendritic cells in a more efficient manner to generate immune responses against tumor antigens, including the applicability of CD40L to target adenoviral vectors for selective and efficient gene transfer to dendritic cells.

Note, too, classification of tumor antigens as tumor-specific or tumor-associated antigens is imperfect as many antigens thought to be tumor-specific have turned out to be expressed on some normal cells as well.

The prior art provides for teaching of tumor antigens as tumor-specific and tumor-associated antigens, as well as the obviousness of targeting each category of tumor antigens at the time the invention was made.

From the teachings of the references, a person of ordinary skill in the art would have a reasonable expectation of success at the time the invention was made. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Ledbetter et al. (U.S. Patent No. 7,118,751) in view of Curiel et al. (U.S. Patent No. 6,284,742) (892; of record), Crystal et al. (US 2003/0202963) and Korokhov et al. (US 2004/0147025).
as applied to claims 1-2, 4-12 and 35-42 above
and further in view of Lamikanra et al. (J. Virol. 75: 9654-9664, 2001) (1449: #A63).

The teachings of Ledbetter et al. (U.S. Patent No. 7,118,751) in view of Curiel et al. (U.S. Patent No. 6,284,742) (892; of record), Crystal et al. (US 2003/0202963) and Korokhov et al. (US 2004/0147025) are set forth above and differ by not explicitly teaching E7 of human papilloma virus as a targeted tumor antigen.

Lamikanra et al. teach targeting E7 of human papilloma virus as a target antigen of treating tumors of interest (see entire document).

Given the teachings herein, it would have been obvious to one of ordinary skill in the art to substitute E7 of human papilloma virus as the tumor antigen of interest in the making and using adenoviral expression vectors comprising CD40L, including the extracellular domain of CD40L with a tumor antigen to stimulate antitumor responses to tumors of interest as taught above. From the teachings of the references, a person of ordinary skill in the art would have a reasonable expectation of success at the time the invention was made. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1, 2, 4-12 and 35-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable
over claims 41, 43-60 and 80-88 of copending USSN 10/997,055.

The claims are drawn to same or nearly the same adenoviral expression vectors and/or nucleic acids encoding a tumor antigen and CD40L.

While there may be election of species as it reads on distinct tumor antigens in the claimed constructs,

The copending constructs comprising nucleic acids encoding mucins would anticipate the generic constructs comprising tumor antigens herein.

Mucins comprised known tumor antigens that would have been substituted into the instant constructs comprising CD40L by the ordinary artisan at the time the invention was made.

The claimed functional attributes of the instant and copending claims are either explicitly or implicitly encompassed by one another as both the instant and copending claims are drawn to CD40-targeted vectors delivering antigen-expressing genes to dendritic cells in a more efficient manner to generate immune responses against tumor antigens, including the applicability of CD40L to target adenoviral vectors for selective and efficient gene transfer to dendritic cells.

Note, too, classification of tumor antigens as tumor-specific or tumor-associated antigens is imperfect as many antigens thought to be tumor-specific have turned out to be expressed on some normal cells as well.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

11. Claims 1, 2, 4-12 and 35-42 30-46 are directed to an invention not patentably distinct from claims 41, 43-60 and 80-88 of commonly owned USSN 10/997,055 for the reasons above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No., discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

12. Given the number of copending applications by the inventorship, applicant is invited to clarify which applications should be subject to rejections under the judicially created doctrine of obviousness-type double patenting.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

Primary Examiner
Technology Center 1600
Art Unit 1644
May 9, 2011